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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,742	10/14/2003	Bernardino Ghetti	1857-ARTI.0253US	4053

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/684,742	GHETTI ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) *1-16,22,24 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21, 25, 26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 11-20-06 has been entered. Claims 17, 18, 22, 25 and 28 have been amended. Claims 1-22 and 24-28 are pending. Claims 17-21, 25, 26 and 28 are under consideration.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17-21, 25, 26 and 28 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility and is repeated for the reasons set forth in the preceding Official action mailed 8-14-06. Applicant's arguments filed 11-20-06 have been fully considered but they are not persuasive.

Applicants cite page 79, lines 4-11 and Figure 4 and argue that the FTL variant transgenic animals could be used to develop screening methods to screen therapeutic agents to identify those capable of modulating FTL variant activity. Applicants further cite page 38 and argue that the claimed transgenic animal has credible, specific and substantial utilities (amendment, p. 9-11). This is not found persuasive because of the reasons set forth in the preceding Official action

mailed 8-14-06. Page 79 of the specification discusses the pathology of **human patient** having mutated FTL gene and Figure 4 discloses the sequence of SEQ ID No. 1. The specification fails to provide any support for the phenotype of the claimed **transgenic animal**. The pathology of a human patient cannot be extrapolated into the phenotype of a transgenic animal. The specification fails to provide a correlation between the altered ferritin light chain gene and phenotype, if any, of the claimed transgenic animals or mice or a correlation between the phenotype, if any, of the claimed transgenic animals or mice and any ferritin light chain gene related disease or disorder. The specification fails to disclose any phenotype of the claimed transgenic animal or transgenic mouse at the time of the invention. A transgenic animal or transgenic mouse having no phenotype is indistinguishable from a wild-type animal or mouse and does not have a specific and substantial utility or a well-established utility because one skilled in the art would not know where and what to look for in using said transgenic animal or mouse.

4. Claims 17-21, 25, 26 and 28 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicant's arguments filed 11-20-06 have been fully considered but they are not persuasive.

Applicants cite page 55, page 74, lines 21-24, Figures 9-14 and 17, and argue that a hereditary neurodegenerative disorder termed hereditary ferritinopathy is associated with a genetic defect in the coding region of the FTL gene and discuss the phenotype of said disorder

(amendment, p. 11-12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 8-14-06 and the reasons set forth above. The specification fails to provide any support for the phenotype of the claimed **transgenic animal**. The pathology of a human patient cannot be extrapolated into the phenotype of a transgenic animal. The specification fails to disclose any phenotype of the claimed transgenic animal or transgenic mouse at the time of the invention. The claimed transgenic animals lack a specific and substantial and well-established utility, therefore, one skilled in the art clearly would not know how to use the claimed invention.

Applicants cite Dr. Vidal's declaration and argue that the transgenic mice with altered FTL gene have intranuclear and intracytoplasmic ferritin deposits, and other phenotypes. Therefore, the claimed transgenic animal has real world use supported by a specific utility (amendment, p. 12-13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 8-14-06 and the reasons set forth above. It is noted that a specific and substantial and well-established utility has to be present at the time of filing an invention, however, the instant invention fails to provide a specific and substantial and well-established utility for the claimed transgenic animal, including transgenic mice. The post-filing declaration by Dr. Vidal fails to fulfill the utility requirement at the time of the invention. Further, the specification fails to disclose the phenotype of intranuclear and intracytoplasmic ferritin bodies in any type of cells in the claimed transgenic animal. Thus, the post-filing declaration by Dr. Vidal cannot be used to support the enablement of the claimed transgenic animal. Therefore, the claims remain rejected under 35 U.S.C. 101 and 112 first paragraph.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17-21, 25, 26 and 28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed 8-14-06. Applicant's arguments filed 11-20-06 have been fully considered but they are not persuasive.

Applicants argue that if the experimentation is routine, then there is no undue experimentation required. The specification discloses methods to generate transgenic animals and one skilled in the art can effectively apply these methods to produce the transgenic animals. Applicants further argue that predicted results and prophetic examples are permitted in patent applications and the specification needs not contain a working example as long as the experimentation is not undue (amendment, p. 14-16). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 8-14-06. The specification fails to disclose any phenotype of the claimed transgenic animals or transgenic mice. A transgenic animal or transgenic mouse having no phenotype is indistinguishable from a wild-type animal or mouse and one skilled in the art at the time of the invention would not know how to use the claimed transgenic animals or mice. Although the methods of making transgenic animal are known in the art, however, the art of transgenics at the time of the invention held that the

resulting phenotype of a transgenic animal or mouse was unpredictable at the time of the invention. The individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct, the site of integration, etc., are the important factors that governs the expression of a transgene in transgenic animals. The genetic background of the transgenic animal also has a large impact on the resulting phenotype of the transgenic animals or mice. Absent adequate guidance and evidence for the phenotype of the claimed transgenic animal, one skilled in the art at the time of the invention would not know how to use the claimed transgenic animal and would require undue experimentation to practice over the full scope of the invention claimed.

Applicants cite declaration by Dr. Vidal and argue that the declaration shows the phenotype of a transgenic mouse over-expressing a human FTL cDNA carrying the FTL TC-insertion after nucleotide 498 under the control of mouse prion protein gene promoter (amendment, p. 16). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 8-14-06 and the reasons set forth above. The post-filing declaration by Dr. Vidal fails to fulfill the utility requirement at the time of the invention. Further, the specification fails to disclose the phenotype of intranuclear and intracytoplasmic ferritin bodies in any type of cells in the claimed transgenic animal. Thus, the post-filing declaration by Dr. Vidal cannot be used to support the enablement of the claimed transgenic animal. It also should be noted that the claims encompass numerous different transgenic animals, such as mice, rats, dogs, feline, sheep, pigs, horses, monkey, baboons, chimpanzee, whales, other mammals, birds, insects, arthropods, and fishes etc. No phenotype of those claimed transgenic animals has been disclosed in the instant invention at the time of filing. The

claims also encompass chimeric animals or mice and a host cell isolated from the claimed chimeric mouse but applicants fail to address such issue.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 17-20 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the reasons set forth in the preceding Official action mailed 8-14-06. Applicant's arguments filed 11-20-06 have been fully considered but they are not persuasive.

Applicants argue that the sequence of FTL variant gene is provided in the specification along with the phenotype associated with hereditary ferritinopathy and Dr. Vidal's declaration describes generation of FTL-variant transgenic mice with desired phenotype. Applicants argue that the specification and the amended claim provide sufficient identifying characteristics of the methods of the invention to meet the written description requirement (amendment, p. 17-18). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 8-14-06 and the reasons set forth above.

Applicants request rejoining withdrawn claim 22 with the product claims (amendment, p. 19). The product claims remain rejected for the reasons of record, therefore, claim 22 cannot be rejoined for examination.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 17-21, 25, 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment filed 11-20-06 necessitates this new ground of rejection.

Claim 17 has been amended to recite the transgenic animal exhibits intranuclear and intracytoplasmic ferritin bodies, which is considered new matter. Applicants cite page 79, lines 4-11 and Figure 4 for the support of this amendment. However, page 79 discusses the pathology of **human patient** having mutated FTL gene and Figure 4 discloses the sequence of SEQ ID No. 1. The specification fails to provide any support for the phenotype of the claimed **transgenic animal**. The pathology of a human patient cannot be extrapolated into the phenotype of a transgenic animal. Thus, there is no support for the phenotype of the claimed transgenic animal

as amended. Therefore, the subject matter of claim 17 is considered new mater. Claims 18-21, 25, 26 and 28 depend from claim 17.

Conclusion

No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER